UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KIMBERLY GREMO, Plaintiff, v. BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER HEALTHCARE PHARMACEUTICALS, INC.; GE HEALTHCARE, INC.; GENERAL ELECTRIC COMPANY; MALLINCKRODT, INC.; MALLINCKRODT LLC; GUERBERT LLC; LIEBEL-FLARSHEIM COMPANY LLC; AMERISOURCE BERGEN CORPORATION; AMERISOURCE BERGEN DRUG CORPORATION, Defendants.	Civil Action No. 1:19-cv-13432-NLH-AMD Honorable Noel L. Hillman, U.S.D.J. Honorable Ann Marie Donio, U.S.M.J. **ORAL ARGUMENT REQUESTED** **Motion Day: October 21, 2019**

REPLY IN SUPPORT OF DEFENDANTS BAYER CORPORATION, BAYER HEALTHCARE LLC AND BAYER HEALTHCARE PHARMACEUTICALS INC.'S MOTION TO DISMISS THE AMENDED COMPLAINT

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Plaintiff's Opposition does not meaningfully address the arguments in Bayer's Motion to Dismiss.[1, 2] ***First***, Plaintiff agrees that her claim of "gadolinium retention" is not a legally cognizable injury. ***Second***, Plaintiff identifies nothing to show that her claims survive federal preemption. ***Third***, Plaintiff's claims are time-barred under New Jersey's two-year statute-of-limitations for product liability claims. ***Fourth***, Plaintiff's claims fail under New Jersey law and federal pleading rules. Bayer accordingly requests dismissal with prejudice.

I. PLAINTIFF CONCEDES THAT "GADOLINIUM RETENTION" IS NOT A FREESTANDING LEGALLY COGNIZABLE INJURY

Plaintiff concedes that gadolinium "retention"—meaning trace amounts of gadolinium remain in a patient's body for some time—cannot serve as a freestanding legally cognizable injury. *See* Pl. Opp. to Mallinckrodt Mot. to Dismiss, Dkt. No. 85 at 19 n.7. That is unsurprising because Plaintiff claims that her injuries are ***symptoms*** supposedly ***resulting from*** retention—not retention itself. *See* Am. Compl. ¶ 166. *See also* Bayer Mot. at 25-26.

II. CLAIMS BASED ON PLAINTIFF'S OTHER ALLEGED INJURIES ARE PREEMPTED

Plaintiff fails to rebut Bayer's preemption arguments. Bayer Mot. at 4-15. Specifically, Plaintiff has not "plead[ed] a labeling deficiency that [Bayer] could have corrected using the ['Changes Being Effected,' or 'CBE'] regulation." *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019) (quotation marks omitted); *see also In re Celexa & Lexapro Mktg.*

[1] Plaintiff's Opposition repeatedly includes vague language purporting to "incorporate" other arguments, but without any references to specific pages, briefs, or arguments. *See, e.g.*, Pl. Opp. at 4-5 (stating that Plaintiff "incorporates all her preemption arguments by reference," but without citing any particular document), 10 (stating that Plaintiff "has already responded" to Bayer's arguments, but not saying where). Bayer asks that the Court ignore these requests.

[2] Defendants Bayer Corporation, Bayer Healthcare LLC and Bayer Healthcare Pharmaceuticals Inc. will be collectively referred to as "Bayer." Plaintiff Kimberly Gremo will be referred to as "Plaintiff."

& Sales Practices Litig., 779 F.3d 34, 41 (1st Cir. 2015) (similar). Contrary to Plaintiff's assertions, *Gibbons* and *Celexa* correctly applied federal preemption principles and no court of appeals has disagreed with them. They are also consistent with *Merck Sharp & Dohme Corp. v. Albrecht*, in which the defendants conceded that the plaintiffs had satisfied the CBE regulation—the point Bayer emphatically disputes here. 139 S. Ct. 1668, 1675 (2019).

Further, Plaintiff does not even mention—let alone distinguish—opinions from three federal courts all finding preempted failure-to-warn claims in cases alleging injury from retained gadolinium from Magnevist exposure in patients with normal kidney function. *See McGrath v. Bayer HealthCare Pharm. Inc.*, 393 F. Supp. 3d 161 (E.D.N.Y. 2019); *Klein v. Bayer HealthCare Pharm. Inc.*, No. 2:18-cv-01424, 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019); *Goodell v. Bayer HealthCare Pharm. Inc.*, No. 18-cv-10694, 2019 WL 4771136, at *3 (D. Mass. Sept. 30, 2019). Critically, ***all three*** cases post-date *Albrecht*.

A. *Gibbons, Celexa, McGrath, Klein*, and *Goodell* Are Consistent with *Albrecht* and Show that Plaintiff Must Plead a Labeling Deficiency that Could Have Been Corrected Using the CBE Regulation

Plaintiff incorrectly claims *Albrecht* overruled voluminous authority stating that she must plead facts satisfying the CBE regulation—an argument courts have squarely rejected. Analysis of FDCA preemption proceeds in two steps. ***First***, "a plaintiff must plead 'a labeling deficiency that Defendants could have corrected using the CBE regulation.'" *Gibbons*, 919 F.3d at 708 (brackets omitted); *McGrath*, 393 F. Supp. 3d at 168-69 (same); *Klein*, 2019 WL 3945652, at *5 (same); *Goodell*, 2019 WL 4771136, at *4 (same). Only ***after*** a plaintiff satisfies that burden does the ***second*** step arise: "the party asserting a preemption defense [must] demonstrate that there is 'clear evidence that the FDA would not have approved a change' to the prescription drug's label." *Gibbons*, 919 F.3d at 708 (brackets omitted); *see also In re Celexa*, 779 F.3d at 41.

Albrecht—and *In re Fosamax*[3]—addressed only the second step, concerning "clear evidence" that the FDA would have rejected a label change. 139 S. Ct. at 1672. Indeed, in *Albrecht*, the Court noted that the CBE regulation must first allow a manufacturer to change its prescription-drug label before the "clear evidence" issue arises. *Id.* at 1673, 1679. But the *Albrecht* defendant "***conceded*** that the FDA's ***CBE regulation would have permitted [it] to try to change the label*** to add [the desired] warning." *Id*. at 1675 (emphasis added). Thus, the *Albrecht* Court's analysis only considered the second, "clear evidence" test, and the two-step analysis articulated in *Gibbons* and *In re Celexa* continues to be consistent with *Albrecht*. *McGrath* explained as much, writing that "[i]n *Albrecht*, the drug manufacturer conceded that the FDA's CBE regulation would have permitted it to try to change the label to add a warning," which differed from *McGrath*, where "Plaintiff has not pleaded a plausible claim that the CBE regulation would have permitted Bayer to change the Magnevist label to reflect *risks* associated with gadolinium retention."[4] 393 F. Supp. 3d at 170 (quotation marks and brackets omitted).

Further, requiring Plaintiff to plead facts satisfying the CBE regulation is appropriate because "federal law ***expressly forbids*** a manufacturer from changing its label after the label has received FDA approval ***unless*** such changes are made pursuant to the ['Changes Being Effected,' or 'CBE'] regulation." *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184-85 (S.D.N.Y. 2016) (emphasis added). Because labeling changes are prohibited by default, plaintiffs must plead that their claims fit within the narrow exception where a manufacturer is permitted to

[3] *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268 (3d Cir. 2017), is the Third Circuit opinion reversed by *Albrecht*.

[4] Plaintiff also claims *Wyeth v. Levine*, 555 U.S. 555 (2009), absolves her of the need to show the CBE regulation is satisfied. That is not so. There, the Court stated that evidence showed the defendant could have satisfied the CBE regulation. *Id.* at 569.

act.[5] That is also why the Supreme Court has dismissed claims at the motion-to-dismiss stage after determining that the manufacturer could not use the CBE regulation to change its drug label. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (dismissing claim where it was not possible for the defendant to use "the CBE regulation . . . to unilaterally strengthen its warning" (quotation marks omitted)).

B. Plaintiff Identifies No "Newly Acquired Information" That Would Have Permitted Bayer to Add a Warning to Magnevist's Label

Plaintiff identifies no new evidence showing a "reasonable evidence of a causal association" between gadolinium retention from Magnevist and any "clinically significant" "adverse reaction[]," as was required to change Magnevist's label. *See* Bayer Mot. at 7-11.

1. Plaintiff points to nothing permitting Bayer to add her proposed warning at the relevant time

Plaintiff does not show that her allegations satisfy the CBE regulation. As Bayer's Motion argued, *see* Bayer Mot. at 7-11, and as Plaintiff does not dispute, *see* Pl. Opp. at 4-7, Plaintiff must show that Bayer could have satisfied the CBE regulation's requirements to add Plaintiff's desired warning—that gadolinium retention causes adverse health effects in patients with normal kidney function—based on information arising between ***June 10, 2014 and July 15, 2014***. That is because Plaintiff claims she used Magnevist only once, on July 15, 2014, Am. Compl. ¶ 164, which means the FDA gave approval in June 2014 for the label that was operative

[5] This general prohibition accompanied by a limited exception distinguishes pharmaceutical labeling from other areas where federal law prohibits only a small minority of private activities. *See, e.g.*, *Bedoya v. Am. Eagle Express Inc.*, 914 F.3d 812, 824 (3d Cir. 2019) (holding that federal aviation laws did not preempt state claims because the claims had no "effect on [air] carrier prices, routes, or services," the federal statute's narrow area of coverage).

when she used the product.[6] *See Goodell*, 2019 WL 4771136, at *4 (claims preempted where "complaint does not cite any newly acquired information that arose after the FDA's approval of Magnevist's revised label in 2007 and before Plaintiff was administered Magnevist in 2010"); *Maze v. Bayer Healthcare Pharm. Inc.*, No. 4:18-cv-21, 2019 WL 1062387, at *2 (E.D. Tenn. Mar. 6, 2019) (similar). Plaintiff ***does not respond*** to Bayer's argument that the Complaint includes no information occurring between June 10, 2014 and July 15, 2014. *See* Bayer Mot. at 8-9. That means her claims are preempted.

Plaintiff also fails to dispute Bayer's argument that nothing in the Complaint would have permitted Bayer to add Plaintiff's desired warning at ***any time*** before she used Magnevist in July 2014. She ignores this argument in her response to Bayer. In her response to ***Mallinckrodt***, Plaintiff points only to two specific articles—one released in 2018 and another in 2017. *See* Pl. Opp. to Mallinckrodt Mot. at 14-15. Both articles were thus published after Plaintiff used Magnevist in 2014, and Bayer could not have given Plaintiff additional warnings based on these post-use publications. Moreover, ***neither*** article showed new evidence demonstrating a causal association between gadolinium retention from Magnevist and negative symptoms in humans with normal kidney function. One considered the effects of gadolinium on rats, not humans, and identified only gadolinium retention, not any adverse effects, in the rats.[7] The other, a review article presenting no new evidence, said reports that GBCAs cause negative symptoms in persons with normal kidney function "are anecdotal" and GBCAs have "an excellent overall safety

[6] *See* Coronato Cert., Ex. C, 6/2014 Magnevist Letter at 1, 3, https:// www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/019596Orig1s057,021037Orig1s030ltr.pdf; Coronato Cert., Ex. D, June 2014 Magnevist Label, https:// www.accessdata.fda.gov/drugsatfda_docs/label/2014/019596s057lbl.pdf.

[7] Lohrke, Histology and Gadolinium Distribution in the Rodent Brain, 52 Invest. Radiol. (2017), https:// www.ncbi.nlm.nih.gov/pubmed/28323657 (abstract).

profile."[8] Plaintiff otherwise refers without explanation to numerous pages of her Complaint without addressing Bayer's arguments showing why those allegations are irrelevant. *See* Bayer Mot. at 9-10; Pl. Opp. at 2, 4-5.

2. Plaintiff does not argue that the FDA was unaware of any information in the Complaint

Nor does Plaintiff dispute that her Amended Complaint fails to allege information unknown to the FDA—an independent reason her claims are preempted. Bayer Mot. at 11. Bayer can only change Magnevist's label based on "newly acquired information" that "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to the FDA." *Gibbons*, 919 F.3d at 708 (citation omitted). Plaintiff does not allege such information.

C. Clear Evidence Shows that the FDA Would Have Rejected Plaintiff's Proposed Label Change

Plaintiff also fails to rebut Bayer's independent argument that "clear evidence" shows the FDA would not have approved the warning she desired. The "clear evidence" standard generally requires that the FDA was "fully informed . . . of the justifications for the warning" Plaintiffs claim was needed, "and that the FDA, in turn . . . would not approve changing the drug's label to include that warning."[9] *Albrecht*, 139 S. Ct. at 1678.

Plaintiff mischaracterizes the 2018 class-wide GBCA label change and OptiMark's 2016 label change—both regarding gadolinium ***retention***—to argue that the FDA would have

[8] Runge, Dechelation, 53 Invest. Radiol. 571, 576 (2018), https:// boris.unibe.ch/125584/1/ Dechelation__Transmetalation___Consequences_and.1.pdf.

[9] Despite claiming otherwise, Plaintiff cites no case requiring the manufacturer to have proposed a specific label to the FDA to demonstrate "clear evidence" that a given warning would have been disallowed. *See, e.g.*, Pl. Opp. to Mallinckrodt at 8.

permitted Bayer to warn of ***negative symptoms allegedly caused by retention***.[10] *See* Pl. Opp. at 7; Pl. Opp. to Mallinckrodt Mot. at 9; Am. Compl. ¶¶ 152-53. That is wrong. In *Davis v. McKesson Corp.*, a federal court explained that the 2017 FDA Advisory Committee Plaintiff discusses, *see* Pl. Opp. at 7, decided that no such warning was appropriate after thorough investigation of exactly this subject. *See Davis*, No. 18-cv-1157, 2019 WL 3532179, at *5 (D. Ariz. Aug. 2, 2019). As *Davis* recounted, "[t]he [advisory committee's] chair . . . summarized the committee's views in these words: 'I think there is fair uniformity that there is no evidence of a causal relationship between the symptoms and signs in patients with normal renal function and the retention of gadolinium.'" *Id.* (emphasis added). That statement, along with the FDA's approval of the 2018 Magnevist label—a formal agency action—which states that "clinical consequences of gadolinium retention have not been established in patients with normal renal function," exhibits by "clear evidence" that the FDA would have rejected the desired warning.

D. Any Design Defect Claim Is Preempted

Plaintiff also fails to rescue her design defect claim. Plaintiff's "design defect" theory is that Bayer should have stopped selling Magnevist and instead sold its product Gadavist. Pl. Opp. to Mallinckrodt at 15-17. But the Supreme Court explicitly rejected such reasoning in *Mut. Pharm. Co., Inc., v. Bartlett*, stating that requiring a drug manufacturer "not to make [a given product] at all" is "incompatible with our pre-emption jurisprudence." 570 U.S. 472, 488 (2013). The Court explained that "if the option of ceasing to act defeated a claim of impossibility,

[10] Both the OptiMark label change and the 2018 class-wide label change came ***after*** Plaintiff used Magnevist. And neither states gadolinium retention from GBCAs harms persons with normal kidneys. As Plaintiff pleads, OptiMark's label stated that "GBCAs have been associated with the development of NSF in patients with renal impairment," but "[t]he clinical significance of gadolinium retention in the body and brain is otherwise unknown." Am. Compl. ¶ 153.

impossibility pre-emption would be 'all but meaningless.'" *Id.* Further, *Bartlett* explained that "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients,'" which preempts state law requiring manufacturers to "alter [the] composition" of a drug. *Id.* at 477, 490; *see also Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015).

III. PLAINTIFF'S CLAIMS ARE TIME-BARRED

Plaintiff failed to rebut Bayer's statute-of-limitations argument based on a January 2015 GoFundMe page where Plaintiff's husband sought to raise funds for Plaintiff's chelation therapy—a treatment frequently used by persons claiming "gadolinium toxicity" or "Gadolinium Deposition Disease." *See* Bayer Mot. at 15-18. In response, Plaintiff erroneously claims that this Court may not ever consider "extrinsic facts" in weighing a motion to dismiss. *See* Pl. Opp. at 8. That is not so. "When considering a Rule 12(b)(6) motion . . . the Court may consider '***items subject to judicial notice***, matters of public record, orders, [and] items appearing in the record of the case." *In re Valeant Pharm. Int'l, Inc., Sec. Litig.*, No. 15-cv-7658, 2019 WL 2724075, at *3 (D.N.J. June 30, 2019) (emphasis added). Here, Bayer asked the Court to take judicial notice of the GoFundMe page. *See* Bayer Mot. at 16-17 & n.10.

Further, Plaintiff does not explain how the treatment referenced in the GoFundMe page for "metal poisoning" related to anything other than "gadolinium toxicity" or "Gadolinium Deposition Disease." *See* Bayer Mot. at 16-17; Pl. Opp. at 9-10. Instead, without any authority,

Plaintiff makes vague claims about the ***possible*** uses of "chelation therapy" for other conditions. *See* Pl. Opp. at 9. Bayer reiterates its request for dismissal on statute-of-limitations grounds.[11]

IV. PLAINTIFF'S CLAIMS ARE BARRED BY STATE-LAW DOCTRINES AND FEDERAL PLEADING RULES

A. Plaintiff's Claims Are Barred by New Jersey's Super-Presumption of Adequacy for FDA-Approved Warnings

Plaintiff also fails to overcome New Jersey's super-presumption of adequacy. Plaintiff agrees that she must rebut the super-presumption to succeed on her claims, agrees that state law provides only three ways to do so, and concedes that her Complaint fails to satisfy one of the three. *See* Bayer Mot. at 19-21; Pl. Opp. at 10-11. But in an effort to dodge the presumption, Plaintiff cites ***state pleading standards*** purportedly showing she need not plead facts clearing the presumption. Pl. Opp. at 11. That is a mistake: claims in federal court are governed by ***federal***, not state, pleading standards. *See, e.g.*, *Adams v. Teamsters Local 115*, 214 F. App'x 167, 175 (3d Cir. 2007). And under federal standards, the "complaint must set forth . . . allegations respecting all the material elements necessary to sustain recovery." *Egli v. Chester Cty. Library Sys.*, No. 18-cv-4012, 2019 WL 3777032, at *2 (E.D. Pa. Aug. 12, 2019) (quotation marks omitted). For that reason, federal courts have held that plaintiffs must plead facts satisfying similar state presumptions. *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 976 (S.D. Tex. 2012) (granting motion to dismiss where plaintiff "identified no . . . exception" to Texas presumption of non-liability). Further, Plaintiff's single sentence claiming that she has satisfied two of these standards utterly fails to address Bayer's contrary arguments. *See* Pl. Opp. at 10-11; Bayer Mot. at 20-21.

[11] Plaintiff's one-sentence reference to tolling does not explain how she was unaware of any claim when the GoFundMe page demonstrates otherwise.

B. Plaintiff's Express Warranty Claim Should Be Dismissed Because Plaintiff Failed to Plead a Specific Warranty.

Plaintiff ignores Bayer's argument that her express-warranty claim is insufficiently specific and must be dismissed. *See* Bayer Mot. at 21-23 (citing *Mendez v. Shah*, 28 F. Supp. 3d 282, 294 (D.N.J. 2014)). In *Shah*, the court rejected the plaintiff's claim that an express warranty was conveyed via "sale and marketing personnel" in "literature, on-line and in television or other advertising" as merely a "general averment" failing to "allege the specific affirmation, promise or guarantee made by [the defendant]." *Id.* at 295. Here, likewise, Plaintiff alleged that Bayer "expressly warranted, by way of affirmation, promise, and/or description in their product labeling, marketing, advertising, promotion, and educational efforts" that Magnevist is generally safe for people with normal kidneys. Am. Compl. ¶ 209. Plaintiff failed to plead any ***specific*** warranty, how it became the basis of a bargain, and how it was breached. Bayer Mot. at 22.

C. Plaintiff Concedes that "Count IV" Does Not Make Any Claims

Plaintiff clarifies that her fourth count does not allege any independent claims. Pl. Opp. at 11. Bayer respectfully requests that the Court's order on this motion reflect that concession.[12]

D. New Jersey Law Bars Plaintiff's Request for Punitive Damages

Plaintiff similarly fails to overcome Bayer's argument that punitive damages for FDA-approved drugs are barred by the NJPLA, and that the New Jersey Appellate Division has held that the sole exception to that bar is preempted. Bayer Mot. at 24-25 (citing *McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10, 94 (App. Div. 2008)). Plaintiff's Opposition to Mallinckrodt concedes that "in *McDarby*, the New Jersey appellate court held that a plaintiff's proof under Section 58C-5(c)"—the sole exception to the punitives bar—"would amount to a claim of 'fraud

[12] Bayer reserves its right to challenge Plaintiff's inadequate allegations of fraud if she later argues that the statute of limitations should be tolled.

on the FDA' and would thus be preempted under the Supreme Court's holding in *Buckman*." Pl. Opp. to Mallinckrodt at 21.

Plaintiff argues that "*McDarby*'s interpretation of *Buckman* was simply wrong and should not be applied here," *id.* at 21, even though *McDarby* has been adopted by this Court and New Jersey appellate panels. *See, e.g., Stanger v. APP Pharms.*, LLC, No. 09-cv-5166, 2010 WL 4941451, at *4 (D.N.J. Nov. 30, 2010); *Baker v. APP Pharms.*, No. 09-cv-05725, 2010 WL 4941454, at *4 (D.N.J. Nov. 30, 2010) (same). Plaintiff relies on a single, widely criticized case, *Forman v. Novartis Pharm. Corp.*, 793 F. Supp. 2d 598 (E.D.N.Y. 2011). In rejecting *Forman*'s analysis, another court "fail[ed] to see a relevant distinction" between the fraud-on-the-FDA claims precluded by *Buckman* and the sole exception to the New Jersey punitive damages statute, since the statute allows punitive awards only when a defendant "knowingly withheld or misrepresented information required to be submitted under the agency's regulations," N.J.S.A. § 2A:58C-5. *See Guenther v. Novartis Pharm. Corp.*, No. 6:08-cv-456, 2013 WL 1225391, at *4 (M.D. Fla. Mar. 27, 2013). Bayer thus asks the Court to decline Plaintiff's invitation to rewrite New Jersey law.

E. Plaintiff Fails to Plead an Injury That Was Reasonably Foreseeable to Bayer

Plaintiff fails to rebut Bayer's argument that, like the plaintiff in *McGrath*, she did not "adequately plead[] that her injuries were . . . ***reasonably foreseeable*** to Bayer." 393 F. Supp. 3d at 172 (emphasis added). Plaintiff's opposition to Bayer ignores the point, and her opposition to Mallinckrodt fails to address Bayer's arguments explaining why none of her allegations demonstrate that gadolinium retention from Magnevist harms persons with normal kidney function. Bayer Mot. at 9-10. Instead, Plaintiff cites broad swaths of her Complaint and offers conclusory statements about NSF, a condition that she admits only affects persons with impaired

kidney function and which has never been diagnosed in anyone with normal kidneys. *See* Bayer Mot. at 10, 26-27; Pl. Opp. to Mallinckrodt at 19. She also claims her physician diagnosed her with "GDD," but does not explain how this purported diagnosis put Bayer on notice of claimed injuries before she used Magnevist in 2014.[13] Pl. Opp. to Mallinckrodt at 19.

CONCLUSION

Bayer respectfully requests dismissal with prejudice.

Dated: October 15, 2019

Respectfully submitted,

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[13] Plaintiff did not cure her failure to plead in accordance with Rule 8's requirements, and Bayer also requests dismissal on that basis. *See* Bayer Mot. at 28.